

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORP.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION

2:12-md-2326

THIS DOCUMENT RELATES TO:

MDL NO. 2326

All Wave 7 Cases

**PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANT'S
MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF
PLAINTIFFS' EXPERT, JIMMY M. MAYS, PH.D.**

Plaintiffs respond to Defendant Boston Scientific Corporation's, (hereinafter "BSC") Motion to Exclude Plaintiffs' expert, Jimmy W. Mays, Ph.D., as follows:

I. INTRODUCTION

BSC has filed a *Daubert* motion to exclude certain opinion testimony of Dr. Jimmy Mays. [Doc. #8330]. BSC does not challenge Dr. Mays' qualifications or fundamental general opinions regarding polypropylene, oxidative degradation of polypropylene *in vivo*, or the effect of *in vivo* degradation on BSC's polypropylene mesh implants when used as a permanent medical implant. BSC asks the Court to adopt here its ruling on a different report in a different case. BSC Mem. at 1 ("Boston Scientific asks the Court to adopt its prior rulings relating to Dr. Mays's general causation opinions set forth in its order in *Frankum v. Boston Scientific*."). First, the only opinion challenged in *Frankum* was the reliability of Dr. Mays' TGA testing. *See Frankum v. Boston Sci. Corp.*, 2015 WL 1976952, at *14-*15 (S.D.W. Va. May 1, 2015). As the Court noted in that case,

As an initial matter, BSC attempts to incorporate by reference its *Daubert* objections to Dr. Mays's general causation opinions offered in *Sanchez v. Boston Scientific Corp.* BSC does not inform the court what these objections are or attach

the *Sanchez* motion. Further, the expert report offered in *Sanchez* was authored by both Dr. Mays and Dr. Guido and is not identical to the report offered in the present case. Accordingly, I will not address the objections made in *Sanchez* and instead rule solely on the issues currently before me.

Id., fn. 15. Accordingly, BSC is asking the Court to enter an order that merely “exclude[s] Dr. Mays’s opinions based on his TGA. . . .” *Id.* at *15. As the Court held in *Sanchez*, Dr. Mays’ opinions are reliable on bases independent from the TGA testing:

. . . [B]ecause Dr. Mays indicates that he relied primarily on other scientific sources, I FIND that Dr. Mays is permitted to testify generally about polypropylene degradation based on his experience and review of the literature. . . . Dr. Mays explicitly states that he relied not only on his knowledge and experience, but also on scientific literature, which are sufficiently reliable methods for forming his particular opinion. Accordingly, I FIND that Dr. Mays is permitted to testify generally that polypropylene is susceptible to oxidation and degrades, without specifically referencing the unreliable testing he conducted with Dr. Guido.

Sanchez v. Boston Sci. Corp., 2014 WL 4851989, *29 (S.D.W. Va. Sept. 29, 2014). *See also Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 538-39 (S.D.W. Va. 2014) (affirming the holding in *Sanchez* that Dr. Mays’ opinions on polypropylene and degradation were reliable because they were “based on his experience and review of scientific literature”). Accordingly, even if BSC receives the full measure of relief it seeks in its motion, Dr. Mays may still testify as to his general opinions about polypropylene, polypropylene, oxidative degradation of polypropylene *in vivo*, or the effect of *in vivo* degradation on BSC’s polypropylene mesh implants when used as a permanent medical implant. Those opinions are based upon sound scientific sources, including Dr. Mays’ experience and his detailed review of the literature.

Dr. Mays issued a new report in his field of expertise, polymer science. *See generally*, Expert Report of Jimmy Mays, Ph.D. (“Mays Report”), attached hereto as **Exhibit “A”**. Dr. Mays is a Professor Emeritus in the Department of Chemistry at the University of Tennessee, where he previously held appointments as a Distinguished Professor of Chemistry with a co-appointment as

a Distinguished Scientist at the Oak Ridge National Laboratory, and where he also held an appointment as Professor in the University of Tennessee, Institute of Biomedical Engineering. *Id.* at 2. Over the past 40 years, Dr. Mays “ha[s] worked extensively in the area of polymer materials”—and specifically with polypropylene polymers. *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 532 (S.D.W. Va. 2014).

II. DR. MAYS’ OPINIONS AT ISSUE

BSC does not challenge Dr. Mays’ qualifications or fundamental general opinions regarding polypropylene, oxidative degradation of polypropylene *in vivo*, or the effect of *in vivo* degradation on BSC’s polypropylene mesh implants when used as a permanent medical implant. Instead, BSC moves to exclude three discrete portions of Dr. Mays’ opinions: (1) his reliance upon a peer-reviewed publication in a highly respected journal in his field; (2) purported opinions about “why Phillips Sumika Polypropylene Company began including the ‘Medical Application Caution’ on the Marlex Polypropylene MSDS in 2004”; and (3) undisclosed opinions that BSC contends are impermissible state of mind or corporate ethics opinions. BSC Mem. at 2, 5-7.

Assuming for the sake of argument that BSC’s motion is granted in its entirety, Dr. Mays may still offer his expertise in opining on the above three categories of opinions at the trial of these matters, as he has done previously at trials involving BSC in the Southern District of West Virginia, the Southern District of Florida, and the Central District of California. Moreover, the plaintiffs’ verdicts in the Southern District of West Virginia and the Southern District of Florida—where Dr. Mays opined to the jury on the subject matters of his report, expressly including the three subject matters set forth *supra*—were affirmed on appeal by the Fourth and Eleventh Circuit Courts of Appeals. *See Campbell v. Boston Scientific Corp.*, 882 F.3d 70 (4th Cir. 2018); *see also Eghnayem v. Boston Scientific Corp.*, 873 F.3d 1304 (11th Cir. 2017).

Second, BSC's challenges in the instant motion are misplaced and should be denied. Dr. Mays, just as any other expert including BSC's own materials general experts, relies upon peer-reviewed scientific literature in respected journals in his field of expertise. Doing so is an accepted method of reaching his conclusions, and BSC takes issue with only one article of many upon which Dr. Mays relies. BSC challenges Dr. Mays' "state of mind" opinions about "the potential reasons behind Phillips Sumika and Chevron Phillips' addition of the MSDS Medical Application Caution in 2004." BSC Mem. at 7. However, BSC cites to no portions of Dr. Mays expert report where he gives such opinions, and thus has failed to mount an adequate challenge. Further, Dr. Mays' opinions regarding the Medical Application Caution relate to the scientific soundness and reliability of the warning, and not that third party's state of mind in drafting the warning. Finally, BSC challenges opinions of Dr. Mays that purportedly address BSC's state of mind or corporate ethics but identify only a single statement from Dr. Mays' report. BSC Mem. at 7-8 (citing Mays Report at 5). Plaintiffs agree the Court has previously excluded that single statement but submit that the motion must be denied as to any other statements because BSC fails to identify them, precluding Plaintiffs' ability to respond in a meaningful way.

III. ARGUMENT AND AUTHORITIES

The Supreme Court's comments to Federal Rule of Evidence 702 reflect that "a review of the case law after *Daubert* shows that the rejection of expert testimony is the exception rather than the rule." Official Comments to the 2000 amendments to Rule 702, FED. R. EVID. In the same official comments that rejected the effort to codify *Daubert* factors into Rule 702, the Supreme Court reiterated, "all of these factors remain relevant . . . yet no single factor is necessarily dispositive." *Id.*; see also *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 594. (1993). "Moreover, *Daubert* did not work a 'sea change over federal evidence law,' and 'the trial

court's role as gatekeeper is not intended to serve as a replacement for the adversary system.” Official Comments to 2000 Amendment to Rule 702, FED. R. EVID. *Accord United States v. Stanley*, 533 F. App'x 325, 327 (4th Cir. 2013) *cert. denied*, 13-6950, 2014 WL 210687 (U.S. Jan. 21, 2014).¹

This Court's scrutiny of Dr. Mays may ultimately rest in *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999), which focuses on a “methodology” challenge through the prism of whether the expert utilizes the same level of “intellectual rigor” in testifying that he/she does in normal professional activities. On one side, the Court may ask whether the expert brings the same level of “intellectual rigor” to the courtroom that he/she uses in his normal day job. *Id.* On the other side, the Court examines whether the expert's opinions seem to be “litigation driven.” *Id.* The Fourth Circuit has adopted this “intellectual rigor” analysis, in light of the 2000 amendments and comments to Rule 702. *See e.g., Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 200 (4th Cir. 2001); *Coleman v. Union Carbide Corp.*, 2013 WL 5461855 (S.D.W. Va. Sept. 30, 2013).

When determining the reliability of an expert opinion, the *Daubert* analysis considers these factors: “whether a theory or technique can be or has been tested; 2) whether it has been subjected to peer review and publication; 3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and 4) whether the theory or technique

¹ This is consistent with the views of how to harmonize “Law” and “Science” as set forth in the 2011 Federal REFERENCE MANUAL ON SCIENTIFIC EVIDENCE: THIRD EDITION. As Justice Breyer himself recognized “the search is not a search for scientific precision. . . . The law must seek decisions that fall within the boundaries of scientifically sound knowledge.... Furthermore, science itself may be highly uncertain and controversial with respect to many of the matters that come before the courts.” *Id.* at 4. Justice Breyer reminds us all that the exercise of judicial discretion in the *Daubert* context must be made with a keen Article III sensitivity to the “basic human liberties . . . guaranteed by our Constitution's Seventh Amendment . . . the right to a trial by jury.” *Id.* at 5. “Any effort to bring better science into the courtroom must respect the jury's constitutionally specified role – even if doing so means that, from a scientific perspective, an incorrect result is sometimes produced.” *Id.*

enjoys general acceptance within a relevant scientific community.” *Smith & Nephew, Inc.*, 259 F.3d at 199 (citing *Daubert*, 509 U.S. at 592-94).

A. Dr. Mays’ Reliance on Published, Peer-Reviewed Literature is Proper and Reliable.

Dr. Mays’ opinions about polypropylene in this case derive from decades of experience with and analysis of polymer characterization and a review of all relevant, peer-reviewed scientific literature. Additionally, Dr. Mays reviewed hundreds of internal BSC documents and scientific articles. Mays Report at 28-32; *id.* at Ex. “B” (Mays Reliance List). His opinions are based upon his experience, knowledge, and review of documents and articles. Polypropylene’s susceptibility to oxidative degradation is a scientific and chemical fact, and his opinions about BSC’s polypropylene products follow from this fact. In addition, Dr. Mays relied on scientific literature and BSC-produced documents about polypropylene generally and the specific polypropylene resins and anti-oxidants used in BSC’s mesh products. *See* Mays Report at 14. Dr. Mays reviewed polypropylene literature that addressed not only oxidative degradation, but also the clinical performance of meshes that degrade in the pelvis. Mays Report at 7–13, 15-26. Dr. Mays relied upon more than 350 sources for his opinions, ranging from scientific and medical literature to BSC internal documents and the BSC meshes themselves. *See* 28-32; *id.* at Ex. “B” (Mays Reliance List). Therefore, Dr. Mays used the methodology in this case that has consistently satisfied this Court’s *Daubert* scrutiny in transvaginal mesh MDLs. *See Tyree*, 54 F. Supp. 3d at 537–39 (admitting Dr. Mays’s opinions about Boston Scientific’s polypropylene); *In re: Ethicon, Inc.*, No. 2:12-md-2327, 2016 WL 4958282 (S.D.W. Va. Aug. 25, 2016) (admitting Dr. Mays’s opinions about Ethicon’s polypropylene).

BSC moves to exclude testing performed by Dr. Mays that it concedes “Dr. Mays does not include . . . in his report for these cases on its face.” BSC Mem. at 2. Instead, BSC takes issue with

Dr. Mays' inclusion of a published, peer-reviewed article authored in part by Dr. Mays as one of many literature references in his report. As an initial matter, exclusion of a single article referenced by Dr. Mays out the many that underpin his reliable opinions—regarding the chemical properties of polypropylene, its oxidative degradation *in vivo*, and the effects on the human body—has no effect on the reliability of those opinions, and BSC does not claim otherwise.

Regardless, Dr. Mays's reliance on a publication that Dr. Mays co-authored in the journal of *Biomaterials*—the *Imel* study²—survives *Daubert* scrutiny despite the Court's prior holdings as to Dr. Mays' testing of BSC's products. Mays Report (at Ex. "B" (Mays Reliance List) at 6). The journal of *Biomaterials* is "the top peer-reviewed journal in the area of biomaterials," including polymer biomaterials, and is regularly cited among polymer chemists. *See Ex. "C"*, Mays Coloplast Dep. at 107:7–20, 108:16–18, 114:10–116:10.³ In 2015, the *Biomaterials* journal published Dr. Mays's testing, data, and conclusions from the Boston Scientific MDL in the *Imel* study. *See Ex. "B"*, *Imel* Study at 1, 11. Before publication, the journal of *Biomaterials* subjected Dr. Mays' testing to the peer-review process. *Ex. "C"*, Mays Coloplast Dep. at 109:12–110:2. Because *Imel* contained testing conducted in litigation, the editorial advisory board for *Biomaterials* also reviewed the methodologies and opinions in *Imel* for scientific merit. *Id.* at 110:11–111:16. Hence, Dr. Mays's methodologies and opinions *twice* passed the *Biomaterials* journal's rigorous peer-review process. *See id.* 114:18–116:110. Even though this Court excluded Dr. Mays's testing, Dr. Mays can rely on *Imel* because *Imel* is a "stud[y] reasonably relied upon in the field of polymer science." *Tyree*, 54 F. Supp. 3d at 538 (quoting *Sanchez*, 2014 WL 4851989,

² *See Ex. "B"*, *Imel et al., In-Vivo Oxidative Degradation of Polypropylene Pelvic Mesh*, 73 BIOMAT. 131-41 (2015).

³ BSC did not question Dr. Mays on the reliability or quality of the journal in which his article was published. Fortunately, Dr. Mays has testified in another pelvic mesh case about those topics and certain relevant portions are referenced for evidentiary purposes here.

at *51). Therefore, BSC's complaint about the *Imel* study "goes to the weight of [Dr. Mays's] opinion, not its admissibility, and can be addressed on cross examination." *Id.* (quoting *Sanchez*, 2014 WL 4851989, at *51). In other words, the Court is presented with a different record than it had when it excluded Dr. Mays' testing. That testing has now been through a rigorous peer-review process—twice—in the foremost journal for polymer chemists. Dr. Mays may rely on this published literature just as any expert may. The alternative would be to subject all scientific literature to mini-*Daubert* challenges, which is an undertaking that would overwhelm the Court and the parties. Instead, BSC's challenge is now to the weight of the evidence and not to its admissibility, and Dr. Mays should be allowed to rely upon his published, peer-reviewed literature.

Finally, regardless of the outcome of BSC's motion on the *Imel* paper, "Dr. Mays is permitted to testify generally about polypropylene degradation based on his experience and review of the literature." *Tyree*, 54 F. Supp. 3d at 538. In this MDL, Dr. Mays based his opinions about polypropylene and oxidative degradation on Boston Scientific-produced documents, his experience, and review of the literature. *Id.* The Court has already found that because Dr. Mays "relied not only on his knowledge and experience, but also on scientific literature," Dr. Mays's methodology was "sufficiently reliable." *Id.* at 539. This Court held, "Dr. Mays is permitted to testify generally that polypropylene is susceptible to oxidation and degrades." *Id.* Dr. Mays should not be precluded from relying upon *Imel* as published in the peer-reviewed journal *Biomaterials*. However, even if he is, such exclusion has no effect on the admissibility of his fundamental general opinions about polypropylene, oxidative degradation of polypropylene in vivo, and the effects of that degradation on polypropylene devices implanted in women.

B. Dr. Mays Is Not Offering Opinions Regarding Phillips Sumika's or Chevron Phillips' State Of Mind.

BSC attempts to limit Dr. Mays' testimony by mischaracterizing his opinions as "state of

mind” testimony. BSC challenges Dr. Mays’ “state of mind” opinions about “the potential reasons behind Phillips Sumika and Chevron Phillips’ addition of the MSDS Medical Application Caution in 2004.” BSC Mem. at 7. However, BSC cites to no portions of Dr. Mays expert report where he gives such opinions. There are none. The only reference to “Phillips Sumika/Chevron Phillips” in Dr. Mays report is contained on a single page and is silent as to any “state of mind” or “potential reasons behind Phillips Sumika and Chevron Phillips’ addition of the MSDS Medical Application Caution in 2004.” *See* Mays Report at 14. Dr. Mays’ opinions regarding the Medical Application Caution relate to the scientific soundness and reliability of the warning, and not that third party’s state of mind in the warning’s drafting. In other words, it is sound science to “caution[] against using the material in the human body” in light of the facts set out in Dr. Mays report: that “the human body attacks foreign materials with strong oxidizing agents including hydrogen peroxide”, and the Technical Service Memo for BSC’s polypropylene resin “cautions against exposure to strong oxidizing agent[s] such as peroxides.” Mays Report at 14. This is not supposition of state of mind, it is application of science to facts and rendering an expert opinion. BSC’s motion to exclude purported “state of mind” opinions should be denied.

C. Dr. Mays Is Not Offering Opinions Regarding BSC’s State Of Mind or Corporate Ethics.

BSC alleges that Dr. Mays attempts to offer opinions concerning BSC’s knowledge or corporate ethics in place of expert testimony “[i]n several places in his report” (BSC Mem. at 7) but cites just one example. Dr. Mays opines in one sentence in his report that “BSC did not take into account polypropylene’s propensity for oxidation during design of its seven pelvic repair meshes.” Mays Report at 5. Plaintiffs acknowledge that the Court has previously excluded this opinion. *See, e.g., Sanchez v. Boston Sci. Corp.*, 2014 WL 4851989, at *30 (S.D.W. Va. June 13, 2016). Respectfully, Dr. Mays’ statement is not a commentary on BSC’s state of mind, but an

observation that BSC failed to consider oxidative degradation when designing its pelvic mesh devices. To the extent the Court is disinclined to change its mind, Plaintiffs understand its ruling and will not elicit this testimony at trial.

BSC cites to no other opinions of Dr. Mays that allegedly concern BSC's knowledge, state of mind, or corporate ethics. Plaintiffs cannot respond to arguments that have not been made, and respectfully submit that this particular challenge should either be denied in whole or granted in part as to the statement identified *supra* and denied as to the remaining other alleged statements that remain unidentified.

III. CONCLUSION

The opinions rendered by Dr. Mays in this litigation are reliable, relevant, and will assist the trier of fact. These opinions are based on review of the applicable peer-reviewed scientific literature and decades of training and research in polymers in both academia and private industry. These opinions were formed years before this litigation commenced and based on settled scientific facts. Dr. Mays' opinions as set forth in his report are largely unchallenged by BSC, and even where BSC does challenge a discrete subset of Dr. Mays' opinions those challenges are misplaced. Plaintiffs respectfully request the Court deny BSC's motion.

Dated: November 18, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 18, 2019, a true and correct copy of Plaintiffs' Memorandum in Opposition to Defendant's Motion to Exclude the Opinions and Testimony of Jimmy Mays, Ph.D. was served via electronic mail with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF counsel of record.

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